UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. (1) ADVOQUE SAFEGUARD, LLC, (2) JASON AZEVEDO, (3) PAUL SHRATER, and (4) ANDREW STACK, Defendants.	)	Criminal No. 24cr10329 MJJ Violations: Count One: Conspiracy to Introduce Misbranded Devices into Interstate Commerce (18 U.S.C. § 371) Count Two: Introduction of Misbranded Devices into Interstate Commerce (21 U.S.C. §§ 331(a) and 333(a)(1)) Forfeiture Allegation: (18 U.S.C. § 982(a)(7))

INFORMATION

At all times relevant to this Information:

General Allegations

1. ADVOQUE SAFEGUARD LLC (ADVOQUE) was a limited liability company formed in Delaware on or about May 26, 2020, with its principal place of business in Santa Clara, California. Prior to the formal creation of ADVOQUE, the owners of ADVOQUE operated a joint venture under a similar trade name.

2. JASON AZEVEDO (AZEVEDO) was a resident of California. AZEVEDO was a co-founder and chief technology officer of ADVOQUE.

3. PAUL SHRATER (SHRATER) was a resident of California. SHRATER was a co-founder and chief business officer of ADVOQUE.

4. ANDREW STACK (STACK) was a resident of California. STACK was a co-founder and chief operating officer of ADVOQUE.

5. JDM Supply LLC (JDM) was a limited liability company formed in Florida by Daniel Motha (D. Motha) on or about March 11, 2020 in response to the COVID-19 pandemic.

6. D. Motha was a resident of Florida. D. Motha co-owned JDM and served as its chief executive officer.

7. Jeffrey Motha (J. Motha) was a resident of Massachusetts. J. Motha co-owned JDM and served as its head of sales.

8. CW-1 was a resident of Massachusetts and a longtime friend of D. Motha and J. Motha. CW-1 was a representative of JDM.

9. In or around the spring of 2020, during the earliest phase of the COVID-19 pandemic in the United States, ADVOQUE and JDM conspired to ship facemasks that were misbranded as NIOSH-approved, N95 respirators. As further described below, one desperate hospital accepted and paid for hundreds of thousands of purported N95 masks that were manufactured by ADVOQUE and sold by JDM. ADVOQUE and JDM misled the hospital into believing that the JDM masks were NIOSH-approved N95s, when in fact they were not.

I. The FDA and the Federal Food, Drug, and Cosmetic Act

10. The United States Food and Drug Administration (FDA) was responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices are safe and effective for their intended uses and bear labeling that contains true and accurate information. The FDA regulated the manufacturing, labeling, and distribution of

medical devices shipped or received in interstate commerce and enforced the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (FDCA).

11. The FDCA prohibited, among other things, the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a misbranded device. 21 U.S.C. § 331(a). A violation of the statute committed with an intent to defraud or mislead would convert the offense from a strict liability misdemeanor to a felony. 21 U.S.C. § 333(a)(2).

12. Under the FDCA, a medical device was misbranded if, among other things, the labeling for the device was "false or misleading" in any part. 21 U.S.C. § 352(a)(1).

13. Under the FDCA, "labeling" was defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

14. Under the FDCA, "interstate commerce" was defined, in part, as "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b).

15. Under the FDCA, a "device" was defined, in part, as "an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, including any component, part, or accessory, which is … (2) intended for use in the [] mitigation . . . or prevention of disease, in man …, and which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(1).

16. Face masks and respirators were "devices" subject to the FDCA when they were intended for a medical purpose, such as prevention of infectious disease transmission (including uses relating to COVID-19).

II. N95 Respirators and NIOSH

17. The arrival of the COVID-19 virus in the United States in early 2020 created an urgent and unprecedent demand among healthcare providers for personal protective equipment, or "PPE." In particular, healthcare providers turned to N95 respirators (often referred to as N95 masks) as a critical last line of defense against this highly contagious and potentially deadly virus.

18. N95 respirators are regulated in the United States by the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH).

19. To be marketed and sold as an "N95" respirator in the United States, a respirator must be evaluated and approved by NIOSH. Under the applicable regulations, an N95 respirator must filter at least 95 percent of airborne particles.[1] A respirator that did not filter at least 95 percent of airborne particles could not be legally marketed or sold in the United States as an "N95" respirator.[2]

20. In connection with the COVID-19 pandemic, the CDC recommended that healthcare workers use N95 respirators in hospitals and other medical treatment environments.

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[1] 42 CFR Part 84, Subpart K § 84.174(i) and § 84.170 to 84.181.

[2] The applicable regulation defined the term N95 to refer to a filter class that removed at least 95% of airborne particles during "worst case" testing using a "most-penetrating" sized particle during NIOSH testing. 42 C.F.R. Part 84.

III. ADVOQUE and JDM Entered the PPE Business in Response to COVID-19

21. Beginning in and about March 2020, the Defendants saw a significant business opportunity in meeting the unprecedented demand for N95 respirators. ADVOQUE, led by AZEVEDO, SHRATER, and STACK, became a mask manufacturer. AZEVEDO was primarily responsible for manufacturing and production of the ADVOQUE mask, including dealing with material suppliers, operating the machines, designing the mask, testing the mask, and dealing with NIOSH. SHRATER and STACK were primarily responsible for the commercial side of the mask business, including sales of the ADVOQUE mask to distributors such as JDM.

22. JDM was a distributor of the ADVOQUE mask. JDM sold the ADVOQUE mask to hospitals, which entered into large purchase orders even before production of the ADVOQUE mask began. D. Motha and J. Motha jointly operated JDM. D. Motha was primarily responsible for finances, sales, and operations, while J. Motha focused on sales.

23. Prior to the COVID-19 pandemic, neither ADVOQUE nor JDM were involved in healthcare or PPE. ADVOQUE (and its predecessor) was a contract manufacturing company whose products included marketing displays for trade shows. JDM did not exist.

24. Both ADVOQUE and JDM recognized that selling N95 respirators to healthcare providers was a million-dollar business opportunity. STACK wrote to his business partners on or about March 8, 2020 regarding their new mask manufacturing venture, "This seems too easy to be making millions." Similarly, on or about March 19, 2020, CW-1 wrote to D. Motha and J. Motha: "Need [ADVOQUE] to come through / like we need them to come through we can make 5 million dollars if they do."

25. On or about March 10, 2020, D. Motha and J. Motha were introduced to STACK in a WhatsApp messaging chat. At that point, the ADVOQUE mask was still in the pre-production phase. STACK wrote to D. Motha, J. Motha, and others: "I need [to] make sure you understand these are not niosh and fda approved yet (although we're fast tracked to be in 2 months hopefully) and they are not fluid [resistant] like the 3M 1860. This is just as if not more effective than all other n95s like the [3M N95 respirator model] 8210."

26. On or about March 15, 2020, STACK created a document outlining a three-step process for testing and approval of the ADVOQUE mask (the "Three-Step Document"), which he sent to D. Motha and J. Motha. The first step was testing and certification of the source material for the mask, which was provided to ADVOQUE by SUPPLIER 1.

27. The second step was testing and certification of the finished ADVOQUE mask, which STACK wrote was "the critical step." ADVOQUE had lined up LAB 1, a nationally recognized lab for N95 certification, to conduct that testing. Based on testing performed on the source material (and provided to ADVOQUE by SUPPLIER 1), ADVOQUE was confident the mask would pass that second step, but as STACK wrote, "The risk of not passing is very low, but not zero."

28. The third step was certification that NIOSH and FDA approved the ADVOQUE mask. However, the Three-Step Document stated that "[t]he product begins shipping after N95 Certification," which ADVOQUE anticipated by early April 2020.

29. Along with the Three-Step Document, STACK provided to D. Motha and J. Motha a copy of a brief letter addressed to AZEVEDO from a representative of SUPPLIER 1. In that letter, the representative stated that the source material provided to ADVOQUE would have a

filtration efficiency of higher than 95%, but added: "To claim the N95 Rating, the finished product needs to be certified by the National Institute for Occupational Safety and Health (NIOSH)."

30. On or about March 17, 2020, STACK wrote to D. Motha and J. Motha on WhatsApp: "We don't ship unless product passes n95. Hospital will get product that meets it. I guess I can't say more than I've already stated in that letter re certification."

31. On or about March 19, 2020, ADVOQUE and JDM executed an agreement for JDM to be a distributor for ADVOQUE. JDM agreed to provide a $20,000 advanced payment for 100,000 units at $1.75 per mask for a total purchase order of $175,000. ADVOQUE represented "that the source material has already been tested and certified N95 compliant." ADVOQUE guaranteed "any funds sent by [JDM] against the representation that the masks will be completed, certified N95 (and FDA and NIOSH will be applied for) and shipped as quickly as possible."

IV. JDM Sold the ADVOQUE Mask to Hospitals as an "N95 Respirator"

32. ADVOQUE told JDM that the ADVOQUE masks would be certified as N95s and approved by NIOSH, expecting that JDM would communicate that to hospitals as part of its sales pitch. JDM then sold the ADVOQUE mask to hospitals as an "N95 respirator."

33. In March 2020, JDM obtained purchase orders for the ADVOQUE mask from three hospital systems: HOSPITAL 1, HOSPITAL 2,[3] and HOSPITAL 3. HOSPITAL 2 ordered 500,000 ADVOQUE N95 masks from JDM, at a cost of $2.50 per mask. HOSPITAL 3 ordered 100,000 ADVOQUE N95 masks from JDM, at a cost of $2.80 per mask but, before receiving any masks, canceled its order due to production delays.

[3] HOSPITAL 2 was based in Massachusetts.

34. On or about the following dates, HOSPITAL 1, a hospital system based in Florida, ordered a total of approximately 850,000 ADVOQUE N95 masks from JDM, on or about the following dates:

Approximate Purchase Order Date	Quantity	Price/Mask	Total
3/17/20	50,000	$2.90	$145,000
3/24/20	100,000	$2.90	$290,000
3/24/20	200,000	$2.90	$580,000
3/30/20	100,000	$3.25	$325,000
4/1/20	200,000	$3.25	$650,000
4/10/20	200,000	$3.25	$650,000

35. HOSPITAL 1 paid JDM 15% of the total cost (approximately $374,000) as a deposit at the time of the purchase order. HOSPITAL 1 paid the remaining balance upon delivery and acceptance of the ADVOQUE masks.

V. JDM Reassured HOSPITAL 1 That the Masks Would Be NIOSH-Approved

36. On or about April 4, 2020, D. Motha wrote to AZEVEDO, STACK, and others on WhatsApp that they had a problem with HOSPITAL 1. D. Motha reported that HOSPITAL 1 was asking about the timeline for NIOSH certification of the ADVOQUE N95 mask, and that HOSPITAL 1 "might cancel some of their order because theyre [sic] not NIOSH."

37. On or about April 8, 2020, at the direction of SHRATER and STACK, INDIVIDUAL 4, a representative and co-owner of ADVOQUE, sent an email to D. Motha with information to reassure HOSPITAL 1. The email attached a new "spec sheet" for the "foldable N95 ADVOQUE mask" that indicated that the mask would be an N95 respirator.

38. D. Motha took that and composed an email to HOSPITAL REP. 1, JDM's main point of contact at HOSPITAL 1. In the email, D. Motha wrote, in part:

> The most important piece to any respirator is their filtration efficiency and that it comes in 95% or higher. The process for certification is at production the masks are reviewed/tested by a testing laboratory, in this case, [LAB 1], which is an international accredited medical testing laboratory. Once testing is complete and they pass, they issue the N95 certification (which should be by the end of next week), and masks can start being shipped out to hospitals. …
>
> Again, I want to make it clear, THESE MASKS WILL BE NIOSH CERTIFIED. …

39. D. Motha's email included the spec sheet as an attachment. The spec sheet thus was part of the labeling that accompanied the ADVOQUE masks to HOSPITAL 1.

40. D. Motha reassured HOSPITAL REP. 1 that "N95 certification" from LAB 1 was coming ("should be by the end of next week") and that the ADVOQUE masks would be NIOSH certified. HOSPITAL 1 did not cancel its order.

VI. JDM's Internal Concerns About the ADVOQUE Mask

41. To help sell the ADVOQUE mask, JDM recruited other individuals to call hospitals on behalf of JDM, including Veterans Affairs (VA) hospitals. INDIVIDUAL 5, a friend of D. Motha, was one of those individuals. D. Motha put INDIVIDUAL 5 in touch with CW-1, the first individual whom D. Motha and J. Motha had recruited to work for JDM.

42. On or about April 17, 2020, INDIVIDUAL 5 raised concerns about the ADVOQUE mask to CW-1 during a text conversation on WhatsApp. Based on the ADVOQUE spec sheet, INDIVIDUAL 5 wrote that the ADVOQUE mask looked "like dog shit" and added: "We're all going to jail I know it."

43. CW-1 reassured INDIVIDUAL 5, based on information D. Motha and J. Motha had provided to CW-1, that the ADVOQUE mask would be NIOSH and N95 certified by the time it was delivered to hospitals.

44. INDIVIDUAL 5 wrote: "If I do jail time I taking [sic] [D. Motha] down w me damn [it]." INDIVIDUAL 5 explained his concerns about the ADVOQUE mask: "Cause it will come out thousands of health care workers got infected and died cause these things are bogus."

45. INDIVIDUAL 5 raised the same concerns to J. Motha. On or about April 17, 2020, INDIVIDUAL 5 texted J. Motha, in reference to the ADVOQUE mask: "Doesn't even recommend for medical/hospital environment use! Oh boy we're all going to jail." J. Motha replied that it did not matter, as all that mattered was that the mask would be "N95 niosh approved." INDIVIDUAL 5 also texted with J. Motha about ADVOQUE, and the pictures of the ADVOQUE management team on the company's website:

INDIVIDUAL 5:	We're all going to get locked up
J. MOTHA:	[AZEVEDO] is a pretty cool guy
	He is the CEO
INDIVIDUAL 5:	Yeah cool enough to get us all locked up by the feds
J. MOTHA:	I don't think so
INDIVIDUAL 5:	When this shot [sic] doesn't work and we infect 5000 nurses

46. INDIVIDUAL 5 questioned whether hospitals would purchase the ADVOQUE mask without NIOSH approval; J. Motha responded: "We have just been saying they are rated

and certified N95 by [LAB 1] which is the most important part and the niosh approval is happening before the end of April."

VII. ADVOQUE Shipped Masks Without Successful Testing or N95 Approval

47. Because of delays, ADVOQUE did not begin producing masks until in or about late April 2020. To start, ADVOQUE produced an ear loop mask, with straps that went around the wearer's ears to secure the mask to their face (as opposed to a "head strap" that went around the back of the wearer's head).

48. ADVOQUE submitted samples of the ear loop mask to LAB 1 for testing to confirm that the finished mask passed the "critical" second step outlined in the Three-Step Document and performed as an N95 respirator. ADVOQUE paid extra for expedited testing. LAB 1, however, informed ADVOQUE that the lab was backed up because of overwhelming demand due to the pandemic, and that the testing on the ADVOQUE mask would be delayed for months, until July 2020.

49. On or about April 30, 2020, ADVOQUE began shipping ear loop masks from its factory in California to HOSPITAL 1 in Florida and HOSPITAL 2 in Massachusetts—without any lab testing on the finished mask, contrary to STACK's March 17, 2020 statement that the product would not ship until it was certified as an N95 respirator.

50. The ADVOQUE ear loop mask was not approved by NIOSH. In early to mid-May 2020, ADVOQUE learned that NIOSH would not certify any mask with an ear loop design as an N95 respirator, but that was not communicated to HOSPITAL 1. Because the mask was not approved by NIOSH, it was not an "N95" and could not be labeled or branded as such. Nor

could the mask be labeled or branded as a "respirator." Instead, it would be classified as a "face mask."

51. ADVOQUE and JDM understood that they could not make representations about the filtration efficiency of the ear loop mask (such as "N95"). For that reason, the ADVOQUE ear loop mask did not say "N95" on it, and the boxes in which the masks were shipped did not say "N95" either. However, ADVOQUE's spec sheet described the masks as N95, and JDM told HOSPITAL 1 and HOSPITAL 2 that they would receive N95 respirators.

52. ADVOQUE began shipping the ADVOQUE mask to HOSPITAL 1 and HOSPITAL 2 in or about late April 2020. HOSPITAL 1 did not use or evaluate the ADVOQUE masks right away but instead kept the ADVOQUE masks in a warehouse as the hospital worked through its remaining supply of other N95 respirators.

53. In or around May 2020, HOSPITAL 2 gave the ADVOQUE mask to its COVID response team for evaluation. A safety officer for HOSPITAL 2 flagged multiple concerns about the ADVOQUE mask, including that the masks did not say "NIOSH Approved[.]" In an email on or about May 5, 2020, the logistics director for HOSPITAL 2's COVID response wrote to other staff at HOSPITAL 2 about the ADVOQUE mask: "what we can tell you is that these 200,000 are not even good to wear as a surgical mask – they literally fall apart in your hands – the straps break the first 20 minutes of being worn. My suggestion is to put them in storage – they really should not even be out where anyone could think they can be used …."

54. On or about May 8, 2020, the purchasing director for HOSPITAL 2, who was JDM's main point of contact, emailed J. Motha (at an email address in CW-1's name) and reported the issues raised by the COVID response team. He wrote in part: "my thought is I can keep what

you sent and what you will send and use them as regular masks but I can't pay $2.50. I am paying .50-.60 for regular procedure masks that I am willing to pay for these. That is the only way these can be used."

VIII. University Lab Testing of ADVOQUE Masks Raised a Red Flag

55. The purchasing director shared an additional piece of information with JDM: HOSPITAL 2 sent a sample of the ADVOQUE masks to be tested by a lab at a Massachusetts-based university ("University Lab") that had volunteered to test PPE during the earliest days of the pandemic.

56. D. Motha forwarded the message to AZEVEDO and STACK, writing: "This is what we were trying to avoid. Please see response below from [HOSPITAL 2]. Really need [LAB 1] testing … I need to provide N95 proof right now."

57. AZEVEDO responded to D. Motha that the source material for the masks "crush the N95 standard" and sent test results from LAB 1, which SUPPLIER 1 had provided to ADVOQUE and purported to be for the source materials for the ADVOQUE mask.[4] JDM and ADVOQUE understood that testing on the source material (step one of the Three-Step Document) was insufficient to represent that the ear loop mask was an N95. As D. Motha wrote to ADVOQUE in a WhatsApp message: "We were promised that [LAB 1] would provide a report that ADVOQUE MASKS ARE N95. The mill can make great material but if the masks aren't put together properly they're not N95."

[4] However, the source materials sent for this testing were different from the source material used to make the masks provided to HOSPITAL 2.

58. On or about May 9, 2020, a University Lab professor emailed the results of the testing on the ADVOQUE mask: the filtration efficiency was 79%, which was below the level the University Lab measured for certified N95s but about average for Chinese-made KN95s. The University Lab professor also explained that the University Lab testing protocol was not the same as the protocol used by NIOSH because the University Lab did not have the same equipment and instead had to approximate the NIOSH protocol for N95 testing.

59. In response to the University Lab testing results, CW-1, D. Motha, and J. Motha texted as follows:

CW-1:	[University Lab] says the mask is N79 Read email
D. Motha:	What email
CW-1:	We are all going to jail just like [INDIVIDUAL 5] said

60. D. Motha forwarded the University Lab testing results to AZEVEDO and STACK. AZEVEDO forwarded the email to SUPPLIER 1, which checked with an expert in the field, who responded that the University Lab test was "not a valid or accurate test for determining N95[.]" AZEVEDO shared that response with D. Motha and J. Motha.

61. JDM forwarded the rebuttal from SUPPLIER 1's expert to the University Lab professor, along with the LAB 1 testing on the source material provided by AZEVEDO. The University Lab professor responded to the points raised in the rebuttal and explained that the testing on the source material was for medical face masks, not N95 respirators. The University Lab professor added: "If you intend to use the ADVOQUE devices as N95's or equivalent, then

I would encourage you to have [LAB 1] run [the NIOSH protocol] for you, if you have not done so already."

62. Based on the University Lab testing, HOSPITAL 2 rejected the ADVOQUE mask, returning the units it had received and cancelling further shipments. HOSPITAL 2 also told JDM that the straps broke easily; as D. Motha wrote to ADVOQUE on or about May 11, 2020: "FYI they also had issues with the bands ripping off so regardless of N95 they want to send them back."

63. HOSPITAL 1 was not told about the issues reported by HOSPITAL 2, the University Lab testing, or the return of the masks by HOSPITAL 2.

64. On or about May 13, 2020, STACK wrote to the other managers of ADVOQUE on WhatsApp: "We owe the JDM guys so much for being our guinea pigs. Strippers and beer as [AZEVEDO] might suggest."

IX. The ADVOQUE Masks Failed N95 Testing by "LAB 2," Which Was Not Disclosed to Hospital 1

65. On or about May 1, 2020, after learning that the LAB 1 testing would be delayed, AZEVEDO contacted a second lab, LAB 2. AZEVEDO arranged for a sample of the ADVOQUE ear loop masks to be tested by LAB 2. On or about May 8, 2020, ADVOQUE submitted the samples to LAB 2. LAB 2 told AZEVEDO that he should expect the results in two to four weeks. STACK also informed JDM that samples of the ADVOQUE ear loop mask had been submitted to LAB 2 for testing. ADVOQUE and JDM hoped that the LAB 2 testing results would show that the ADVOQUE ear loop mask met the minimum standard for an N95 respirator and thus satisfied the "critical step" in testing of the finished mask.

66. On or about May 27, 2020, LAB 2 emailed AZEVEDO the test results, which showed that the ADVOQUE ear loop mask failed to meet N95 standards.

67. HOSPITAL 1 was not told about the failing LAB 2 test results.

68. On or about July 16, 2020, ADVOQUE finally received the results of LAB 1's testing of the ADVOQUE mask, which showed another failure. As the LAB 1 report stated, the samples did "not conform to the NIOSH N95 criteria for filter efficiency." HOSPITAL 1 was not told about those results from LAB 1.

69. JDM understood that the ADVOQUE mask was shipped to the hospitals without a passing test on the finished mask. On or about May 18, 2020, CW-1 and D. Motha texted:

CW-1:	What ever happened with that Nelson lab test
D. Motha:	I feel like it was bullshit! [J. Motha] called [LAB 1] and they said that the date they have for completion is in July
CW-1:	What was? [HOSPITAL 2] or [ADVOQUE]
D. Motha:	The [LAB 1] expedited test
CW-1:	Bunch of frauds
	Like [INDIVIDUAL 5] said we all going to jail

X. JDM Provided HOSPITAL 1 NIOSH Testing and Approval Documents for a Different Mask

70. ADVOQUE and JDM did not have a passing test result for the ADVOQUE ear loop mask that was shipped to HOSPITAL 1. JDM instead sent NIOSH passing test results and approval documents to HOSPITAL 1 for a different mask: a version of the ADVOQUE mask with a head strap attachment. On or about May 27, 2020, pursuant to an expedited, public health emergency procedure adopted by NIOSH, ADVOQUE sought and obtained temporary NIOSH approval for that mask.

71. On or about May 26, 2020, STACK emailed D. Motha and J. Motha with the results of testing by NIOSH on the different ADVOQUE mask, with the note: "pass!!! Official approval coming tomorrow, but you can share test data w [HOSPITAL 1] now. finally, a passing test result that can be shared. still no [LAB 1]. lol." The test results only referred to the mask by a code name and did not specify that the model tested was ADVOQUE's head strap mask—not its ear loop mask. D. Motha forwarded the NIOSH test results to HOSPITAL REP. 1 without stating that the test results only applied to the ADVOQUE head strap masks. In this context, the NIOSH testing results were part of the labeling of the ADVOQUE masks that accompanied the ADVOQUE masks to HOSPITAL 1.

72. On or about May 27, 2020, D. Motha emailed HOSPITAL REP. 1 the NIOSH approval documentation for the different ADVOQUE mask with the note: "Niosh approval for [ADVOQUE masks]." HOSPITAL REP. 1 understood this as confirmation of what D. Motha had previously promised HOSPITAL 1: that the ADVOQUE masks the hospital received would be NIOSH-approved N95 respirators. In this context, the NIOSH approval documentation was part of the labeling of the ADVOQUE masks that accompanied the ADVOQUE masks to HOSPITAL 1.

73. Because the test results and NIOSH approval did not apply to the non-NIOSH, non-N95 masks that were sold and shipped to HOSPITAL 1, these materials rendered the labeling for the masks false and misleading.

74. ADVOQUE understood that sending the NIOSH testing documents related to its head strap model could mislead purchasers of ADVOQUE's non-NIOSH, non-N95 ear loop mask. On or about June 3, 2020, STACK texted on WhatsApp with co-owners of ADVOQUE,

including SHRATER. STACK suggested sending NIOSH test results to a potential buyer of the ADVOQUE ear loop mask and SHRATER replied in part: "I wouldn't do that because that's where you can get into real legal trouble of trying to pass off a non niosh mask as equivalently niosh I think we just have to kind of let it speak for itself."

75. On or about June 9, 2020, two co-owners of ADVOQUE, INDIVIDUAL 4 and INDIVIDUAL 6, texted with each other on WhatsApp. INDIVIDUAL 4 wrote: "Ready to be loaded? We are oceans 11, war dogs and we did it over WhatsApp."

76. On or about June 27, 2020, STACK texted with SHRATER and AZEVEDO on WhatsApp to reflect on their experience with ADVOQUE and a broadcast STACK had heard earlier that day. STACK noted that one guest on the broadcast "was talking about 'billionaire mindset'" and said "their MO is 'ready, fire, aim!'" STACK added:

> And that's if you get a huge order for something… you say YES and then figure out how to make it happen :-)
>
> Related to the mantra of "ask forgiveness instead of permission"

77. When staff at HOSPITAL 1 went to evaluate the ADVOQUE mask, they identified "many safety and compliance issues." On or about June 30, 2020, a purchasing manager at HOSPITAL 1 emailed D. Motha, writing in part: "It seems the clinicians and nurses are complaining about the quality of the masks. They've run into issues with tearing on the ear loops, and sizing where they are too small to fit their faces. They honestly cannot be used for many safety and compliance issues. We have 836K masks on hand, can we return this amount?" D. Motha shared the complaint with STACK, who in turn shared it with AZEVEDO and the other managers of ADVOQUE.

78. On or about the following day, July 1, 2020, CW-1 texted the following to D. Motha and J. Motha:

> "Like [INDIVIDUAL 5] said. He took one look at the mask and said 'we are all going to jail' !!! Lol … I'd def [say] to [ADVOQUE] this is the 3rd hospital plus Canada that has had major concerns with the product."

79. On or about the following dates, ADVOQUE shipped misbranded "N95" masks from California to HOSPITAL 1 in Florida:

a. 1,200 masks on or about May 1, 2020;

b. 900 masks on or about May 2, 2020;

c. 10,350 masks on or about May 5, 2020;

d. 9,900 masks on or about May 7, 2020;

e. 16,200 masks on or about May 8, 2020;

f. 27,450 masks on or about May 11, 2020;

g. 64,350 masks on or about May 15, 2020;

h. 129,600 masks on or about May 19, 2020;

i. 81,000 masks on or about May 22, 2020;

j. 97,200 masks on or about May 29, 2020;

k. 97,200 masks on or about June 1, 2020;

l. 97,200 masks on or about June 4, 2020;

m. 88,250 masks on or about June 9, 2020; and

n. 97,200 masks on or about June 9, 2020.

80. On or about July 3, 2020, D. Motha texted CW-1 and J. Motha a screenshot of a chart showing rising COVID-19 cases, with the note: "Crazy." They then texted as follows:

CW-1:	What about death rates
D. Motha:	They'll come
CW-1:	Yeah because [HOSPITAL 1] trusts your masks

81. In or around July 2020, HOSPITAL 1 demanded a refund for the ADVOQUE masks. Following discussions, ADVOQUE and JDM agreed to accept the return of all masks from HOSPITAL 1 and provide a full refund to HOSPITAL 1 of $1.9 million. HOSPITAL 1 did not use any of the ADVOQUE masks and returned approximately 837,000 masks to ADVOQUE.

82. On or about August 28, 2020, NIOSH's National Personal Protective Technology Laboratory tested a sample of ten ADVOQUE masks that ADVOQUE and JDM had caused to be shipped to HOSPITAL 1. All ten ADVOQUE masks tested between 83.94% and 93.24% filtration efficiency, and thus fell under the 95% minimum level of filtration efficiency required for N95 respirators.

COUNT ONE
Conspiracy to Introduce Misbranded Devices into Interstate Commerce
(18 U.S.C. § 371)

The United States Attorney charges:

83. The United States Attorney re-alleges and incorporates by reference paragraphs 1-82 of this Information.

84. From in or about April 2020 through in or about June 2020, in the District of Massachusetts, and elsewhere, the defendant,

(1) ADVOQUE SAFEGUARD LLC,

conspired with JDM to introduce into interstate commerce misbranded medical devices with the intent to defraud and mislead, that is, the coconspirators conspired to sell and ship masks to HOSPITAL 1 that were misbranded as NIOSH-approved N95 respirators, when in fact the masks were not NIOSH-approved N95 respirators, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

Object and Purpose of the Conspiracy

85. The object of the conspiracy was to deceive HOSPITAL 1 into accepting and paying for approximately 837,000 defective ADVOQUE masks, by assuring HOSPITAL 1 that the masks were NIOSH-approved N95 respirators and providing false and misleading documentation to HOSPITAL 1 to support that false claim. The principal purpose of the conspiracy and the scheme to defraud was to make money and provide cash flow for ADVOQUE and JDM to keep the businesses going and generate profits for their owners.

Manner and Means of the Conspiracy

86. Among the manner and means by which ADVOQUE and JDM carried out the conspiracy were the following:

a. Selling the ADVOQUE mask to hospitals, including HOSPITAL 1, as an

"N95 respirator" without testing on the finished mask or NIOSH approval.

b. Providing marketing materials to induce hospitals to purchase the ADVOQUE mask, including a one-page "spec sheet" that falsely described the ADVOQUE ear loop mask as an "N95 Respirator."

c. Reassuring HOSPITAL 1 that it would receive lab tested, NIOSH-approved N95 respirators after HOSPITAL 1 threatened in early April 2020 to cancel its purchase orders for the ADVOQUE N95 mask because the masks were not NIOSH-approved,

d. Shipping ADVOQUE masks from California to HOSPITAL 1 in Florida without lab testing to confirm that the masks performed as N95 respirators.

e. Shipping ADVOQUE masks from California to HOSPITAL 1 in Florida that were not NIOSH certified, *i.e.*, approved as N95 respirators by NIOSH.

f. Concealing from HOSPITAL 1 testing showing that the ADVOQUE mask did not perform as an N95 respirator, including test results from the University Lab and test results from LAB 2 received by AZEVEDO on or about May 27, 2020, showing that a sample of ADVOQUE masks failed N95 testing.

g. Concealing from HOSPITAL 1 a known defect with the ADVOQUE mask that caused the ear loop straps to break off the mask easily.

h. Providing HOSPITAL 1 with passing test results and approval documents from NIOSH, while concealing that those test results and approval were for a different model of respirator from what ADVOQUE shipped to

HOSPITAL 1.

Overt Acts in Furtherance of the Conspiracy and the Scheme to Defraud HOSPITAL 1

87. On or about April 8, 2020, JDM emailed HOSPITAL REP. 1 with a spec sheet that falsely described the ADVOQUE masks as "N95 respirators" and assured HOSPITAL REP. 1 that the ADVOQUE masks received by the HOSPITAL 1 would be NIOSH-approved, N95 respirators.

88. On or about May 26, 2020, JDM emailed HOSPITAL REP. 1 a copy of passing test results from NIOSH for a different mask, falsely claiming that these test results applied to the ADVOQUE masks that HOSPITAL 1 received from ADVOQUE.

89. On or about May 27, 2020, JDM emailed HOSPITAL REP. 1 a copy of NIOSH approval documentation for the different ADVOQUE mask, falsely claiming that this approval applied to the ADVOQUE masks that HOSPITAL 1 received from ADVOQUE.

90. On or about the following dates, ADVOQUE shipped misbranded "N95" masks from California to HOSPITAL 1 in Florida:

a. 1,200 masks on or about May 1, 2020;

b. 900 masks on or about May 2, 2020;

c. 10,350 masks on or about May 5, 2020;

d. 9,900 masks on or about May 7, 2020;

e. 16,200 masks on or about May 8, 2020;

f. 27,450 masks on or about May 11, 2020;

g. 64,350 masks on or about May 15, 2020;

h. 129,600 masks on or about May 19, 2020;

i. 81,000 masks on or about May 22, 2020;

j. 97,200 masks on or about May 29, 2020;

k. 97,200 masks on or about June 1, 2020;

l. 97,200 masks on or about June 4, 2020;

m. 88,250 masks on or about June 9, 2020; and

n. 97,200 masks on or about June 9, 2020.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO
Introduction of Misbranded Devices into Interstate Commerce
(21 U.S.C. §§ 331(a) and 333(a)(1))

The United States Attorney charges:

91. The United States Attorney re-alleges and incorporates by reference paragraphs 1-82 of this Information.

92. From in or about April 2020 through in or about June 2020, in the District of Massachusetts, and elsewhere, the defendants,

(2) JASON AZEVEDO,
(3) PAUL SHRATER, and
(4) ANDREW STACK,

caused to be introduced into interstate commerce misbranded medical devices, that is, ADVOQUE masks that were sold and shipped to HOSPITAL 1 that were misbranded as NIOSH-approved N95 respirators, when in fact the masks were not NIOSH-approved N95 respirators.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1).

FORFEITURE ALLEGATION
(18 U.S.C. § 982(a)(7))

93. Upon conviction of one or more of the offenses in violation of Title 18, United States Code, Section 371 and Title 21, United States Code, Sections 331(a) and 333(a)(1) set forth in Counts One and Two, the defendants,

(1) ADVOQUE SAFEGUARD LLC,
(2) JASON AZEVEDO,
(3) PAUL SHRATER, and
(4) ANDREW STACK,

shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

94. If any of the property described in Paragraph 93, above, as being forfeitable pursuant to Title 18, United States Code, Section 982(a)(7), as a result of any act or omission of the defendants --

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendants up to the value of the property described in Paragraph 112 above.

All pursuant to Title 18, United States Code, Section 982(a)(7).

JOSHUA S. LEVY
Acting United States Attorney
District of Massachusetts

WILLIAM B. BRADY
HOWARD LOCKER
ASSISTANT UNITED STATES ATTORNEYS
DISTRICT OF MASSACHUSETTS

District of Massachusetts: October 29, 2024